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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,912	04/30/2001	Raxit J Jariwalla	478-P-10	5290

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EXAMINER

COOK, REBECCA

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,912

Applicant(s)

JARIWALLA, RAXIT J

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 5-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant has elected calcium ascorbate as the plasma-soluble metal salt of ascorbic acid and a non-toxic metal salt of an aldonic acid as the Vitamin C metabolite without traverse. Claims 2 and 5-10 are withdrawn as not reading on the elected invention. Claims 1, 3 and 4 will be examined as reading on the elected invention.

Claim Objections

Claim 1 is objected to as containing non-elected subject matter.

Claim Rejections - 35 USC § 112

Claims 1 and 3-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "one or more Vitamin C metabolites. However, the specification recites that the one or more vitamin C metabolites is selected from the group consisting of "aldonic acids, the aldono-lactones, aldono-lactides and non-toxic metal salts of aldonic acids, dehydroascorbic acid, threose, erythreose, 4-hydroxy-5-methyl-3(2H)-furanone, 3-hydroxykojic acid and 5-hydroxymaltol. Furthermore, it is not clear what compounds are intended to be included in the recitation "one or more Vitamin C metabolites." The specification does not set forth any specific metabolites, including when the metabolite is an aldonic acid.

Art Unit: 1614

Additionally on page 1, lines 9-11, the specification recites that the method is for treating cancer in a human host, while claim 1 recites "contacting tumor cells."

Claims 1 and 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 no host or effective amount is recited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,822,816 (Markham) and Riordan.

Markham discloses (column 1, lines 33-34; column 2, lines 34-35) that Vitamin C, including calcium ascorbate, inhibits tumor growth. Riordan (abstract, pages 211-212, "Safety") also discloses that high doses of ascorbic acid are useful to treat cancer, but that they can cause serious side effects. Markham also discloses that high levels of Vitamin C result in undesirable side effects, but that the presence of metabolites of ascorbic acid and its derivatives, which include the instant salts of aldonic acids, are useful to improving human body tolerance to Vitamin C.

Art Unit: 1614

The claims further recite one or more Vitamin C metabolites. However, it would be obvious to one of ordinary skill in the art to combine the instant calcium ascorbate and an aldonic acid salt metabolite of ascorbic acid to yield the instant chemotherapy method because Riordan and Markham disclose that high doses of ascorbic acid can cause serious side effects. One would be motivated to administer an aldonic acid salt metabolite of ascorbic acid in order to reduce the undesirable side effects that high levels of Vitamin C can cause.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-6 of U.S. Patent No. 6,468,980. Although the conflicting claims are not identical, they are not patentably distinct from each other because '980 discloses a method of treating cancer using a vitamin C metabolite. The "comprising" language of '980 would allow for the inclusion of the instant calcium ascorbate.

Art Unit: 1614

Claims 1 and 3-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5 of copending Application No. 10/129,219. Although the conflicting claims are not identical, they are not patentably distinct from each other because '219 discloses a method of treating cancer using a vitamin C metabolite. The "comprising" language of '219 would allow for the inclusion of the instant calcium ascorbate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Application/Control Number: 09/830,912

Page 6

Art Unit: 1614

Rebecca Cook

A handwritten signature in cursive script that reads "Rebecca Cook".

Primary Examiner

Art Unit 1614

September 12, 2004